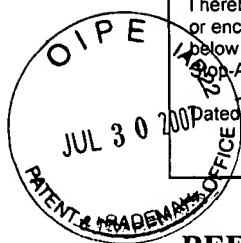


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Dated: 7-30-07 Signature: Carla Rivera
(Carla Rivera)

(PATENT)

**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of:
Richard Lazzara et al.

Application No.: 09/237,605

Art Unit: 3761

Filed: January 25, 1999

Examiner: G. Chapman

For: INFECTION-BLOCKING DENTAL IMPLANT

REQUEST FOR REHEARING OF DECISION ON APPEAL

Mail Stop-Appeal Briefs-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This Request for Rehearing is in response to the Decision on Appeal dated May 30, 2007. This Request for Rehearing is being submitted within two months of the Decision on Appeal, i.e., by July 30, 2007, and is, therefore, timely. The Appellants respectfully request that the Decision on Appeal decided on May 30, 2007 in the above-identified application be reconsidered for the reasons stated below.

I. Status of Claims

The Appellants appealed the Examiner's final rejection of claims 51 and 60-75 under 35 U.S.C. § 103(a) over JP 3-146679 to Haruyuki ("Haruyuki") and U.S. Patent No. 5,571,017 to Niznick ("Niznick"). In the Decision on Appeal, the Board rejected claims 51 and 60-75 under 35 U.S.C. §112, second paragraph, finding that the claims are indefinite. The Appellants respectfully submit that the phrase at issue – "substantially uniform array of irregularities" – is not indefinite.

II. Legal Standard for Indefiniteness

The Appellants respectfully suggest that the claim language in question – “substantially uniform array of irregularities” – is acceptable according to Federal Circuit precedent.

A. “Substantially” Is Commonly Used in Claim Language, Especially When Needed to Provide the Inventor with the Benefit of Protection of the Invention

“In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Bancorp Serv., LLC v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1371 (Fed. Cir. 2004). Furthermore, a claim is definite if its legal scope is clear enough that a person of ordinary skill in the art could determine whether or not a particular composition infringes. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

The Federal Circuit has held that “[e]xpressions such as ‘substantially’ are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention . . . and indeed may be necessary in order to provide the inventor with the benefit of his invention.” *Verve v. Crane Cams, Inc.*, 311 F.3d 1116, 1119-20 (Fed. Cir. 2002). Indeed, “substantially” is recognized as a “descriptive term[] ‘commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.’” *Playtex Prods., Inc., v. Proctor & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005) (quoting *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298 (Fed. Cir. 2003)).

Accordingly, the Federal Circuit has repeatedly found that the word “substantially,” when used as a descriptive term in a patent claim and given its “ordinary and accustomed meaning to one skilled in the art”, is a “meaningful modifier” of approximation that is not ambiguous (*Playtex Prods.*, 400 F.3d at 907) and, instead, has the following easily identifiable dictionary definitions: “considerable in extent,” (*Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1365 (Fed. Cir. 2001) (citing AMERICAN HERITAGE DICTIONARY SECOND COLLEGE EDITION 1213 (2d ed. 1982)), “largely but not wholly that which is specified”

(*Circle R Inc. v. Trail King Indus., Inc.*, 2001 U.S. App. LEXIS 22017 *10 (Fed. Cir. 2001)), “most of the entire [parameter]” (*York Prods., Inc. v. Cent. Tractor*, 99 F.3d 1568, 1573 (Fed. Cir. 1996)), “largely or approximately” (*Cordis Corp. v. Medtronic Ave., Inc.*, 339 F.3d 1352, 1360 (Fed. Cir. 2003); *Dana Corp. v. American Axle & Mfg., Inc.*, 2004 U.S. App. LEXIS 18265 (Fed. Cir. 2004)), “significantly” or “essentially” (*Deering Precision Instruments, LLC v. Vector Distrib. Sys.*, 347 F.3d 1314, 1323 (Fed. Cir. 2003)).

B. It Is Acceptable for Claim Language to Include “Substantially Uniform”

The Federal Circuit has also specifically held that the term “substantially uniform” is not indefinite. In *Cordis*, for example, the court held that “substantially uniform” was sufficiently definite despite a lack of numerical standard in the patent. *Cordis*, 339 F.3d at 1360. The Court in *Cordis* found that the term “substantially” in the context of a patent claim describing a “wall surface having a substantially uniform thickness” denoted “approximation.” *Id.* (citing *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1031 (Fed. Cir. 2002)). The Court concluded that the “substantially uniform” language of the claims was not indefinite and interpreted the language as “the walls must be of largely or approximately uniform thickness.” *Id.*

In *Ecolab*, another case in which the Federal Circuit held that the term “substantially uniform” was not indefinite, the court stated that “nonnumerically limited descriptive claim terms” should be construed using the same rules of construction as any other claim term. *Ecolab*, 264 F.3d at 1365. Thus, in accordance with the rules of claim construction, the Court examined the claim language, the written description, and the prosecution history. *Id.* at 1367. Because no special definition for the terms “substantially,” “uniform,” or “substantially uniform” was found, the court reviewed dictionary definitions of the terms “substantially” (“considerable in extent” or “largely but not wholly that which is specified”) and “uniform” (“always the same in degree; unvarying”). *Id.* (citing, respectively, THE AMERICAN HERITAGE COLLECTION DICTIONARY 1475 (3d ed. 1997), AMERICAN HERITAGE DICTIONARY SECOND COLLEGE ED. 1213 (2d

ed. 1982), and WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 1176 (9th ed. 1983)). The Court concluded that "the use of the term 'substantially' to modify the term 'uniform' does not render the phrase so unclear such that there is no means by which to ascertain the claim scope." *Id.*

III. The Pending Language – "Substantially Uniform Array of Irregularities" – Is Not Indefinite Under 35 U.S.C. § 112

Independent claims 51, 63, and 68 of the present application relate to a titanium dental implant including a surface that is acid etched to produce a "substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns." While this language is at the heart of the current issues regarding 35 U.S.C. § 112, the Appellants note that, as discussed in Section IV below, each of claims 51, 63, and 68 includes other limitations that are important from a patentability standpoint.

A. The Term "Substantially Uniform" Is Required to Describe the Claimed Surface and Would Be Understood by the Skilled Artisan

"Substantially uniform" is used in claims 51, 63, and 68 to modify the term "array of irregularities." According to its plain meaning from the dictionaries used by the Federal Circuit, "uniform" is defined as "having always the same form, manner, or degree; not varying." WEBSTER'S 9TH NEW COLLEGIATE DICTIONARY, 1290 (9th Ed. 1983); *see also Ecolab, Inc.*, 264 F.3d at 1367. However, "uniform" is modified in the claims by the term "substantially," which, as noted above, has an ordinary meaning of "being largely but not wholly that which is specified." *Id.* at 1176; *Circle R*, 2001 U.S. App. LEXIS 22017 *10. Therefore, when given its "ordinary and accustomed meaning" (*Envirotech v. Al George, Inc.*, 730 F.2d 753 (Fed. Cir. 1984)), the language of claims 51, 63, and 68 imports that the irregularities described therein have largely, but not wholly, the same form, manner, or degree.

In fact, the specification describes the surface of Example 3 in a way that is entirely consistent with the dictionary definition above, such that skilled artisan would understand what is meant by "substantially uniform."

The implants were then removed from the acid and rinsed and neutralized by repeating the same steps carried out upon removal of the implants from the HF. All samples displayed very similar surface topographies and a **high level of etch uniformity over the surface**, when compared with each other in SEM evaluations. Consistency in the surface features (peaks and valleys) was also observed. The SEMs in FIGS. 6A, 6B, 7A and 7B show the surfaces of two of the implants, Sample 705MB and Sample 705MC, at magnifications of 2,000 and 20,000. It will be observed that the surface features over the areas shown are consistent and uniform.

Appeal Br. Ex. G, p. 11, ll. 9-16 (emphasis added). By using the term “high level of etch uniformity over the surface,” the specification teaches that the irregularities on the roughened surface were not absolutely or perfectly uniform.

Furthermore, the term “substantially uniform” is appropriate with respect to the present invention, as the photomicrographs in the Figures make clear. For the convenience of the Board, FIGS. 7A and 7B (which are referenced in the previous cited paragraph) are attached as Exhibit A to this Request for Rehearing. At 2000X magnification, for example, it is clear that the surface is not perfectly uniform, but it can be seen to be substantially uniform. As such, the claims are as precise as the subject matter permits. *See Andrew Corp. vs. Gabriel Elec. Inc.*, 6 U.S.P.Q.2d 2010 (1988). One skilled in the art would understand the meaning of “substantially uniform” in view of the description of the etched surfaces in the specification and the photographs of the surfaces.¹

The Decision on Appeal suggests that “a peak-to-valley height of zero or 0.01 microns would fall within [the “substantially uniform”] claim limitation, so that an array of irregularities of **widely varying heights** might be present on the roughened surface.” Decision on Appeal, p. 13-14 (emphasis added). The

¹ The Decision on Appeal states that the Declaration of Prabhu Gubbi does not reach a conclusion of whether the prior art samples contained “substantially uniform arrays of irregularities” in the context of the indefiniteness rejection. *See, e.g.*, Decision Ap. p. 12-13. However, the Gubbi Declaration was **not** submitted to prove definiteness. Rather, the primary purpose of the Gubbi Declaration was to show that surfaces described in the cited references, including Haruyuki, were not reproducible and thus, that the references were not sufficiently enabled.

Appellants do not agree with this statement. An array of irregularities having a portion with irregularities having peak-to-valley heights of 1 to 3 microns and another portion with irregularities having peak-to-valley heights of 0.01 micron would not fall within the scope of the claims. The very purpose of including the term “substantially uniform” is to exclude surfaces in which the irregularities have “widely varying heights” (as suggested in the Decision on Appeal) from the scope of the claims. Thus, although the language of claims 51, 63, and 68 allow for reasonable variance among the irregularities, an array of irregularities having “widely varying heights” would not be substantially uniform and would, thus, fall outside the scope of the claims.

In fact, the specification also indicates that a surface with an array of irregularities having “widely varying heights” would not be substantially uniform. In Example 2, the present specification describes the surface of an implant subjected to bulk acid etching without prior removal of the native oxide layer as “result[ing] in a non-uniformly etched surface, as depicted for example in Figure 3 of U.S. Patent No. 5,876,453” (“the ‘453 patent”). Appeal Br. Ex. G, p. 10, ll. 15, 24-26. Figure 3 of the ‘453 patent is attached as Exhibit B for the convenience of the Board. As can be seen, Figure 3 schematically illustrates a surface that is non-uniform.

Consequently, the Appellants respectfully submit that one of ordinary skill in the art reading the present specification would understand the scope of the “substantially uniform array of irregularities” language of claims 51, 63, and 68.

B. Removing the Word “Substantially” May Unduly Limit the Claim Scope

It is important to consider the ramifications on the scope of the claims if the word “substantially” were removed from claims 51, 63, and 68. In doing so, one must keep in mind that although perfect uniformity of the array of irregularities may be desired, the nature of the roughening process – acid etching on a micro-level – is such that perfect uniformity is impossible to achieve. As such, removing the word “substantially” may cause third parties to argue that the

claims require perfect uniformity of the array of irregularities, which practically speaking, no implant would ever fall within the literal scope of the claim.²

Take, for example, a hypothetical example in which an array of irregularities includes a first group of irregularities having a peak-to-valley height of about 7 microns in the form of cone-shape elements and a second group of irregularity having a peak-to-valley height of about 8 microns in the form of cone-shaped elements that are somewhat wider than the first group of cone-shaped elements. Would the lack of the word “substantially” make it questionable whether such an array of irregularities falls within the scope of the claims? Clearly, limiting the claim scope to exclude an implant having such irregularities would be unduly limiting and would not “protect the inventive contribution” of the Appellants. See *Exxon Research & Eng. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

Even if the term “substantially” were deleted and the skilled artisan read the claims in light of the specification, it is clear that he or she would appreciate that each irregularity in the array of irregularities cannot be identical. Consequently, deleting the term “substantially” would not make the claims more definite, as the term “substantially” helps claims 51, 63, and 68 provide proper protection over the subject matter therein.

C. The Appellants Previously Overcame the Indefiniteness Rejection with Respect to the Word “Substantially” During Prosecution of the Present Application

This is not the first time that the Appellants were faced with a rejection under 35 U.S.C. § 112, second paragraph, based on indefiniteness relating to the term “substantially.” The Appellants argued against the 35 U.S.C. § 112, rejection based on the inclusion of the word “substantially” during the prosecution

² The Appellants would not agree with such a hypothetical argument because the claims would still need to be construed in accordance with the specification and Figures, which make it clear that there is no such thing as a perfectly “uniform array of irregularities” when the surface is acid etched.

of the present application. *See, e.g.*, Amendment and Response to Final Office Action Dated July 23, 2004.

The Examiner agreed with the Appellants that the term “substantially” did not render the claims indefinite. Accordingly, the Examiner withdrew the 35 U.S.C. § 112 rejection in the subsequent Advisory Action mailed on December 9, 2004. The Appellants respectfully request the Board to do the same and withdraw this rejection.

D. The PTO Has Previously Issued Patents to the Appellants Including the Same “Substantially Uniform” Language

Claims containing the words “substantially uniform array of irregularities” have been allowed in several related patents, e.g., the ‘453 patent”, U.S. Patent No. 6,491,723 (“the ‘723 patent”), and U.S. Patent No. 6,652,765 (“the ‘765 patent”).³ These patents are related under 35 U.S.C. § 120 to the present application and are owned by the same assignee. Here are a few examples.

Claim 5 of the ‘453 patent is directed to an implant to be surgically implanted in living bone and states that “the surface resulting from said acid etching consist[s] of a substantially uniform array of irregularities comprising substantial numbers of substantially cone-shaped elements having base-to-peak heights in the range from about 0.3 microns to about 1.5 microns” (emphasis added).

Claim 14 of the ‘723 patent is directed to a method of preparing a surface of an implant made of titanium having “an etched surface with a substantially uniform array of irregularities” (emphasis added). Likewise, claim 19 of the ‘723 patent is directed to a method of preparing a surface of a device that is surgically implantable in living bone, the method including “produc[ing] a surface with a substantially uniform array of irregularities having peak-to-valley heights less than about 10 microns and substantial numbers of said irregularities being cone-shaped elements” (emphasis added). The ‘723 patent also includes

³ The present application is a continuation-in-part of U. S. Patent No. 5,863,201, which is also a continuation-in-part of U.S. Patent No. 5,876,453. U.S. Patent No. 6,491,723 is also a continuation of U.S. Pat. No. 5,876,453.

dependent claims 24, 28, and 36, which state that “a substantially uniform array of irregularities have a peak-to-valley height of less than about 10 microns” (emphasis added).

Claim 1 of the ‘765 patent is directed to a method of preparing a surface of a device that is surgically implantable in living bone. The method includes “produc[ing] a roughened surface with a substantially uniform array of irregularities” (emphasis added). Claim 13 of the ‘765 patent is directed to a method of preparing a surface of a dental implant that is to be surgically implanted in living bone, the method including “produc[ing] a modified--surface with a substantially uniform array of irregularities having peak-to-valley heights less than 10 microns” (emphasis added). Claim 25 of the ‘765 patent is directed to a method of preparing a surface of a dental implant--that is to be surgically implanted in living bone, the method including “produc[ing] a further roughened surface with a substantially uniform array of irregularities having peak-to-valley heights less than 10 microns” (emphasis added).

Because claims including language identical to the language now disputed in the present application have been issued by the Patent Office, withdrawing the rejection under 35 U.S.C. § 112 would be consistent with previous practice as applied to Appellants’ claims. Furthermore, in light of the term “substantially uniform” being present in the claims of the related patents, the present claims should be construed to respect the statutory presumption of validity under 35 U.S.C. § 282 of the Appellant’s previously issued patents and “protect the inventive contribution of [the] patentees.” *Exxon*, 265 F.3d at 1375.

IV. The Appellants Respectfully Request that the Board Review the Remaining Outstanding Prior Art Issues

The Appellants respectfully suggest that the Decision on Appeal seems to oversimplify the issues of this case by stating, “[t]he crux of the dispute revolves around the roughened surface that results from applying the surface treatment of Haruyuki to an implant, and whether this resulting surface is comprised of ‘a substantially uniform array of irregularities’ as claimed.” Decision Ap., p. 10-11. Without question, the “substantially uniform array of irregularities” language is

part of the dispute. However, even if the Board were to find that Haruyuki teaches a substantially uniform array of irregularities, the following points of contention are still present in this dispute:

1. Haruyuki's second step "smoothen" the underlying surface – it does not "roughen" it. Appeal Br., p. 7.
2. Niznick and Haruyuki do not teach all of the elements of claim 51. Appeal Br., p. 9.
3. Niznick and Haruyuki teach away from their combination. Appeal Br., p. 10-11.
4. Niznick teaches away from the claimed invention. Appeal Brief, p. 12.
5. Niznick and Haruyuki do not teach all of the elements of claim 63. Appeal Br., p. 13.
6. Niznick and Haruyuki do not teach all of the elements of claim 68. Appeal Br., p. 14.
7. Niznick and Haruyuki do not teach all of the specific elements of dependent claims 61, 67, and 72. Appeal Br., p. 15.
8. Dr. Porter's Declaration establishes secondary evidence of non-obviousness. Appeal Br., pp 15-17.

The Appellants acknowledge that the Decision indicates that it did not need to address certain patentability issues, such as "the combinability of the references or the evidence presented in the Declaration of Dr. Porter." Decision App., p. 15. However, there are other patentability issues, as indicated above, that would still require the Board's review.

V. Conclusion

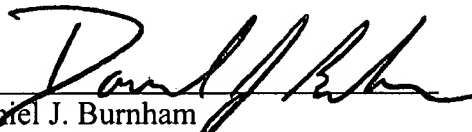
For all the foregoing reasons, claims 51, 63, and 68 are definite as presently written, and the Appellants respectfully request that the indefiniteness rejection based on claims 51, 63, and 68 be reversed and that the Board address the remaining issues related to the current prior art rejections.

Appellants do not believe that any additional fees are due; however, should any additional fees be required (except for payment of the issue fee), the

Commissioner is authorized to deduct the fees from Nixon Peabody LLP Deposit
Account No. 50-4181 (Order No. 247168-35USC1).

Respectfully submitted,

Date: July 30, 2007



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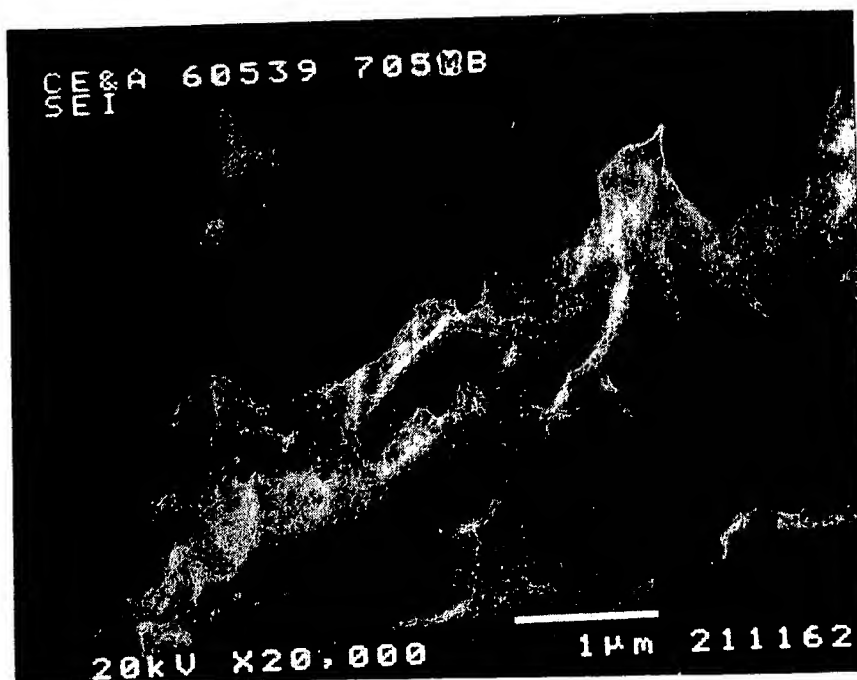


FIG. 7A

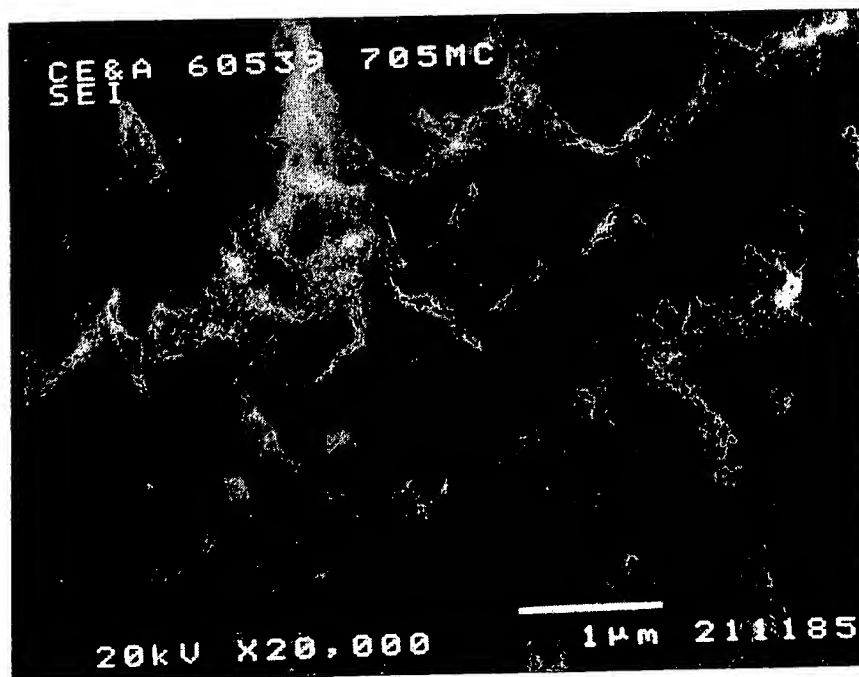


FIG. 7B

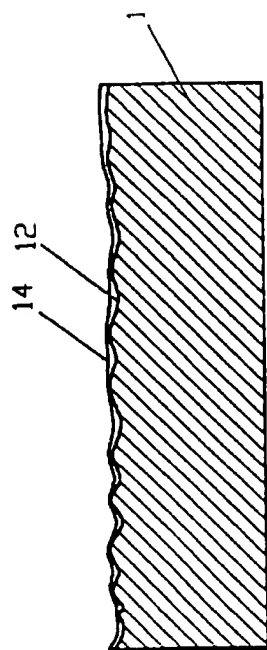


FIG. 2

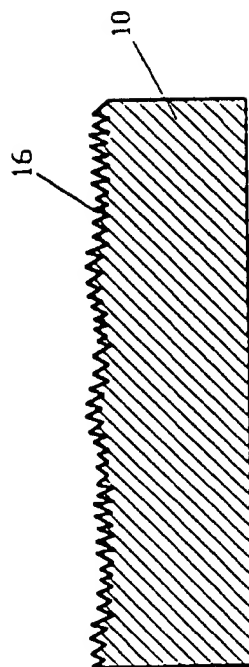


FIG. 4

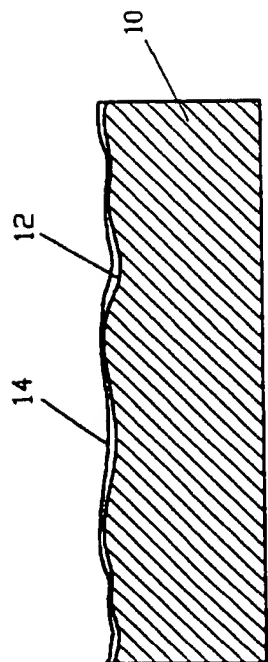


FIG. 1

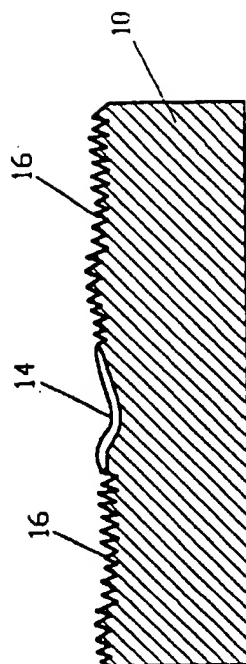


FIG. 3